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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/568,671	02/17/2006	Satoko Yamahira	Q93246	2722

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EXAMINER	
MARX, IRENE	

ART UNIT	PAPER NUMBER
1651	

NOTIFICATION DATE	DELIVERY MODE
01/20/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/568,671	YAMAHIRA ET AL.	
	Examiner	Art Unit	
	Irene Marx	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 November 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *4,6,8,10 and 16-18* is/are pending in the application.

4a) Of the above claim(s) *8 and 10* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *4, 6, and 16-18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/23/09 has been entered.

Claims 4, 6 and 16-18 are being considered on the merits.

Claims 8 and 10 are withdrawn from consideration as directed to a non-elected invention.

Specification

35 U.S.C. 112, first paragraph, requires the specification to be written in "full, clear, concise, and exact terms." The specification is inconsistent in that references to strain *Lactobacillus* ONRIC b0240 (FERM BP- 100605) do not consistently refer to *Lactobacillus pentosus* ONRIC b0240 (FERM BP- 100605). This is now the proper designation for the strain, since the Tajiri declaration is persuasive. An amendment at one location does not suffice.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:
The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 4, 6 and 16-18 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant has successfully argued that the proper designation for *Lactobacillus "plantarum"* ONRIC b0240 (FERM BP-10065) is *Lactobacillus pentosus* ONRIC b0240 (FERM BP-10065). Applicant has amended the specification at one instance to indicate that the strain is properly *Lactobacillus pentosus* ONRIC b0240 (FERM BP-10065). However, the invention as claimed is directed to an improper designation.

In addition, claim 18 raises issues of new matter with the recitation of in an "amount effective to promote human IgA production in mucosae", since portion of the specification relied on for support pertains to the intestinal mucosa, and not to all mucosae, including the respiratory mucosa, for example.

Therefore, the claims are inconsistent with the specification. Correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 4, 6 and 16-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 4, 6 and 16-17 are vague, indefinite and confusing in that the amount effective "to stimulate mucosal immunity" is not set forth with particularity for any and all subjects, which include subjects as diverse as poultry and fish and various mammals ranging from mice to elephants to dogs to cats and to humans, even when reading the claims in light of the specification.

Also, claim 18 is vague and indefinite in that the effective amount to "promote human IgA production in mucosae" cannot be readily ascertained, even when reading the claims in light of the specification. See, also the new matter rejection.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 4, 6 and 16-18 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are broadly to the provision of *Lactobacillus plantarum* ONRIC b0239 (FERM BP-10064) or *Lactobacillus plantarum* (*pentosus*) ONRIC b0240 (FERM BP-10065) in an amount effective to stimulate mucosal immunity in any and all subjects or in humans, respectively for promoting human IgA production in humans. In contrast, the specification only provides broadly stated guidance as to the amount of these strains to be administered to mice.

No guidance is presented regarding the structure/function relationship between the amount provided and the stimulation of mucosal immunity or the promotion of human IgA production. Thus, there is no clear indication of the amounts required to achieve the required claim designated capabilities for the strains for any subject in general or for humans in particular. It is noted that subjects having mucosal immunity include animals such as poultry and fish and mammals as diverse as mice, elephants, dogs, cats and humans. There is no clear indication on this record that the disclosure provided is reasonably predictive of the activity of strains in any and all of these environments. Similarly, There is no clear indication on this record of the amounts that are effective to simulate mucosal immunity in any and all subjects or in humans, respectively for promoting human IgA production in human mucosae.

Given the claim breadth and lack of guidance as discussed above, the specification fails to provide an adequate written description of the claimed invention.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the

examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 4, 6 and 16-18 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Ikenaga *et al.* or Perdigon *et al.* (J. Dairy Sci., 1999, 82:1108-1114) or Herias.

The claims are drawn to *Lactobacillus* compositions which are capable of stimulating mucosal immunity.

The cited references each discloses a *Lactobacillus plantarum* composition which appears to be identical to the presently claimed strain (see, e.g., Abstract; page 1109, col. 2, paragraph 2; page 284, paragraph 3), since the strain is similarly is capable of stimulating mucosal immunity. The referenced composition appears to be identical to the presently claimed strain and is considered to anticipate the claimed composition since the microorganism belongs to the same species *Lactobacillus plantarum* and has similar mucosal stimulating ability. Consequently, the claimed composition appears to be anticipated by the reference.

In the alternative, even if the claimed microorganism is not identical to the referenced microorganism with regard to some unidentified characteristics, the differences between that which is disclosed and that which is claimed are considered to be so slight that the referenced microorganism is likely to inherently possess the same characteristics of the claimed microorganism particularly in view of the similar characteristics which they have been shown to share. Thus the claimed composition would have been obvious to those skilled in the art within the meaning of USC 103.

Accordingly, the claimed invention as a whole was at least prima facie obvious, if not anticipated by the reference, especially in the absence of evidence to the contrary.

Response to Arguments

Applicant's arguments and Yamahira Declarations filed 3/13/09 and 11/23/09 have been fully considered but they are not deemed to be persuasive.

The claims are directed to a food or beverage composition or pharmaceutical compositions comprising a specific strain of *L. plantarum* "capable of stimulating mucosal immunity". However, there is specific amount of the *L. plantarum* strain of interest in the compositions as claimed. There is no clear definition in the specification as to what constitutes

"an amount effective" in this context. The stimulation of mucosal immunity could be due to ingredients in the composition other than the recited strains.

It is emphasized that the claims are not directed to a biologically pure culture of a particular strain, but rather to ingestible compositions, such as various foods or beverages comprising undefined amounts of the cultures. The arguments are not directed to an ingestible composition comprising the strains with any specificity. There is nothing on the record to suggest that traces of dead cells of the strains of interest would have the touted properties. From the specification, it is apparent that 2.0×10^9 cells/mL were used in the activity assays (Specification, page 39). This appears to be a threshold concentration of cells.

It is assumed that the Yamahira declaration is also directed to the use of 2.0×10^9 cells/mL since the same protocol was used. If it is, the declaration and claims should reflect this concentration to provide for a nexus between the claimed invention and the results touted.

There is no clear correlation between the material having the touted unexpected properties and the claimed invention wherein the concentration of the strains of interest is not recited in the claimed composition.

At the concentration of 2.0×10^9 cells/mL it is apparent from the data presented that the strains of interest shown unexpected results over the strain 299v of Herias and ONC141 of Ikenaga *et al.* at least *in vitro*. However, the rejection is maintained on the references, because there is no clear correlation between the results shown testing a specific concentration of live cells and a food or beverage composition or a pharmaceutical composition containing an undisclosed number of cells, including traces, as claimed wherein the effects are *in vivo* in various animals. Oral tolerance must be considered.

The claimed ingestible composition does not provide a patentable distinction over the cited art directed to ingestible compositions comprising strains of the same species *L. plantarum* to be effective *in vivo*. In addition, it is unclear that the touted benefits of human mucosal immunostimulation are effective in the absence of a threshold population of bacteria in the composition, such as 2.0×10^9 cells/mL, and applicant has not shown otherwise.

The scope of the showing must be commensurate with the scope of claims to consider evidence probative of unexpected results, for example. In re Dill, 202 USPQ 805 (CCPA, 1979), In re Lindner 173 USPQ 356 (CCPA 1972), In re Hyson, 172 USPQ 399 (CCPA 1972), In re

Boesch, 205 USPQ 215, (CCPA 1980), In re Grasselli, 218 USPQ 769 (Fed. Cir. 1983), In re Clemens, 206 USPQ 289 (CCPA 1980). It should be clear that the probative value of the data is not commensurate in scope with the degree of protection sought by the claim.

Therefore the rejection is deemed proper and it is adhered to.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Irene Marx whose telephone number is (571) 272-0919. The examiner can normally be reached on M-F (6:30-3:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300 .

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Irene Marx/
Primary Examiner
Art Unit 1651